Date of Approval: May 13, 2004

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION (ANADA)

ANADA 200-310

ESTROPLAN Injection

(cloprostenol sodium)

Beef and Dairy Cattle

It is indicated for intramuscular use to induce luteolysis in beef and dairy cattle. The luteolytic action of ESTROPLAN can be utilized to manipulate the estrous cycle to better fit certain management practices, to terminate pregnancies resulting from mismatings, and to treat certain conditions associated with prolonged luteal function.

Sponsored by:
Parnell Laboratories (Aust) Pty. Ltd.
Century Estate, Unit 6
476 Gardeners Road
Alexandria, New South Wales 2015, Australia

FREEDOM OF INFORMATION SUMMARY

1. General Information:

a. File Number:	ANADA 200-310
b. Sponsor:	Parnell Laboratories (Aust) Pty. Ltd. Century Estate, unit 6 476 Gardeners Road Alexandria, New South Wales 2015, Australia Drug Labeler Code: 068504
c. Established Name:	Cloprostenol sodium
d. Proprietary Name:	ESTROPLAN Injection
e. Dosage Form:	Injectable
f. How Supplied:	20 mL multidose vials
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	Each mL of the colorless aqueous solution contains 263 mcg of cloprostenol sodium equivalent to 250 mcg of cloprostenol.
i. Route of Administration:	Intramuscularly
j. Species/Class:	Beef cattle & dairy cattle
k. Recommended Dosage:	2 mL of ESTROPLAN Injection (500 mcg cloprostenol) should be administered by intramuscular injection for all indications in both beef and dairy cattle.
l. Pharmacological Category:	Luteolytic action
m. Indications:	It is indicated for intramuscular use to induce luteolysis in beef and dairy cattle. The luteolytic action of ESTROPLAN can be utilized to manipulate the estrous cycle to better fit certain management practices, to terminate pregnancies resulting from

mismatings, and to treat certain conditions associated with prolonged luteal function.

n. Pioneer Product: ESTRUMATE; cloprostenol sodium; NADA 113-645; Schering-Plough Animal Health

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and drug effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 2002).

Based on the formulation characteristics of the generic product, Parnell Laboratories (Aust) Pty. Ltd. was granted a waiver from the requirement for an *in vivo* bioequivalence study for the generic product ESTROPLAN Injection (cloprostenol sodium). The generic product is administered as an injectable solution, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, ESTRUMATE (cloprostenol sodium), the subject of Schering-Plough Animal Health, NADA 113-645, was approved on February 2, 1982.

3. HUMAN SAFETY:

· Tolerances for Residues:
A tolerance is not required because one was not required for the pioneer product.

· **Withdrawal Times:**
A withdrawal period is not required because one was not required for the pioneer product.

· **Regulatory Method for Residues:**
A regulatory method is not required because one was not required for the pioneer product.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the Act and demonstrates that ESTROPLAN Injection, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile Generic Labeling and Currently Approved Pioneer Labeling are attached as indicated below:

Pioneer Labeling for NADA 113-645:
ESTRUMATE- 20 mL insert and box

Generic Labeling for ANADA 200-310
ESTROPLAN Injection-20 mL insert, box, and shipping carton